Full Text PA-95-049

MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD

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National Cancer Institute

National Institute of Environmental Health Sciences

National Institute of Mental Health

National Institute of Neurological Disorders and Stroke

National Institute of Nursing Research

National Center for Human Genome Research

National Center for Research Resources

Application Receipt Dates: February 1, June 1, and October 1

PURPOSE

The Mentored Research Scientist Development Award (MRSDA) is for research scientists who need an additional period of sponsored research experience as a way to gain expertise in a research area new to the candidate or in an area that would demonstrably enhance the candidate's scientific career. It is expected that following this experience, the candidate will be able to pursue an independent and productive research career.

The Mentored Research Scientist Development Award (K01) provides an intensive, supervised career development experience in one of the biomedical, behavioral, or clinical sciences. The

proposed experience should be in a research area new to the applicant and/or one in which an additional supervised research experience will demonstrably enhance the candidate's scientific career. The experiences should permit the application of novel or highly promising interdisciplinary approaches to particular research problems. Candidates must justify the need for a three, four, or five year period of mentored research experience and must be able to provide a convincing case that the proposed period of support will substantially enhance his/her career and/or will allow the pursuit of a novel or promising approach to a particular research problem.

Candidates who have interrupted their careers because of illness or pressing family care commitments may apply if they can clearly demonstrate the potential for productive independent research and the need for an additional period of mentored research experience in order to accomplish an effective scientific reentry.

Similarly, faculty members at institutions with a substantial minority enrollment, who wish to enhance their research skills through a supervised research experience at a nearby research center, may also apply, if they agree to remain at their parent institution after completion of the award.

The MRSDA replaces four existing NIH career development mechanisms, including the Research Scientist Development Award (K01), the Minority School Faculty Development Award (K14), the Research Career Reentry Program (K17), and the Scientist Development Award (K21). Individuals who were eligible to apply for any one of these awards are now eligible to apply for a K01 award. Therefore, this Program Announcement (PA) supersedes all previous K01, K14, K17, and K21 program announcements.

The NIH will no longer accept competing applications for the old K01, K14, K17, and K21 awards. Existing policies and provisions will remain in effect for current K01, K14, K17, and K21 recipients until completion of the non-competing years of their three to five year career development program.

Funding institutes and centers may, from time to time, issue PAs or requests for applications (RFAs) that modify the ELIGIBILITY REQUIREMENTS or MECHANISM OF SUPPORT sections of this program announcement in order to meet special program needs such as soliciting applications from specially targeted groups of investigators.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Mentored Research Scientist Development Award, is related to the priority area of human resource development. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

In general, the candidate must have a research or a health-professional doctorate or its equivalent, and must have demonstrated the capacity or potential for highly productive independent research in the period after the doctorate. Applicants for the K01 from the National Center for Human Genome Research, however, may be non-biologists without a doctoral degree such as computer scientists, physicists, mathematicians, and chemists. All applicants are encouraged to contact the prospective NIH awarding component regarding their eligibility for the K01.

The candidate must identify a mentor with extensive research experience, and must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development activities for the period of the award.

Applications may be submitted on behalf of candidates by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education. Minorities and women are encouraged to apply. Candidates must be U.S. citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states, but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

Candidates may have been principal investigators on PHS research grants and may have been supported by a research career award in the past, provided the proposed research experience is a fundamentally new field of study or there has be a significant hiatus in their research career because of family or other personal obligations. Current principal investigators on PHS research grants are not eligible.

MECHANISM OF SUPPORT

Awards in response to this PA will use the K01 mechanism. Planning, direction, and execution of the program will be the responsibility of the candidate and her/his mentor on behalf of the applicant institution. The project period may be for three, four, or five years and will depend upon the number of years of prior research experience, the need for additional experiences to achieve independence, and the policy of each particular institute or center.

Awards are not renewable.

RESEARCH OBJECTIVES

- A. Environment: The institution must have a well-established research and/or clinical career development program(s) and qualified faculty to serve as mentors. The institution must be able to demonstrate a commitment to the development of the candidate as a productive, independent investigator. And, the candidate, mentor and institution must be able to describe a multi-disciplinary career development program that will maximize the use of relevant research and educational resources.
- B. Program: The award provides three to five consecutive 12 month appointments. At least 75 percent of the recipient's full-time professional effort must be devoted to the program and the remainder devoted to other research-related and/or teaching pursuits consistent with the objectives of the award. The candidate must develop knowledge in the basic sciences and research skills relevant to his or her career goals. The candidate may find it appropriate to include relevant didactic and laboratory or field research experiences.
- C. Mentor(s): The recipient must receive appropriate mentoring throughout the three to five year program. Where feasible, women and minority mentors should be involved as role models.
- D. Allowable Costs:
- 1. Salary: The NIH will provide salary and fringe benefits for the K award recipient. The salary limits are not uniform throughout the NIH and are determined independently by each component of the NIH. Therefore, prospective candidates should contact the NIH component to which the application is targeted to ascertain the maximum contribution to the candidate's salary.

The institution may supplement the NIH contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived.

In no case, may PHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the MRSDA. Under expanded authorities, however, institutions may rebudget funds within the total costs awarded to cover salaries consistent with the institution's salary scale.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

- 2. Research Development Support: Most awarding components of the NIH will provide up to \$20,000 per year for the following expenses:
- (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment, and technical personnel; (c) travel to research meetings or training; (d) statistical services including personnel and computer time. The National Institute of Mental Health will provide up to \$50,000 for research development support.
- 3. Ancillary Personnel Support: Salary for mentors, secretarial and administrative assistance, etc., is not allowed.
- 4. Indirect costs: Indirect costs will be reimbursed at eight percent of modified total direct costs, or at the actual indirect cost rate, whichever is less.
- F. Evaluation: In carrying out its stewardship of human resource related programs, the NIH may begin requesting information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.
- G. Other Income: Fees resulting from clinical practice, professional consultation, or other comparable activities required by the research and research-related activities of this award may

not be retained by the career award recipient. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.

The funds may be used for health-related research purposes.

The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks must be made payable to the Department of Health and Human Services, NIH and forwarded to the Director, Division of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Awardees may retain royalties and fees for activities such as scholarly writing, service on advisory groups, or honoraria from other institutions for lectures or seminars, provided these activities remain incidental and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

Usually, funds budgeted in an NIH supported research or research training grant for the salaries or fringe benefits of individuals, but freed as a result of a career award, may not be rebudgeted. The awarding component will give consideration to approval for the use of released funds only under unusual circumstances. Any proposed retention of funds released as a result of a career award must receive prior written approval of the NIH awarding component.

H. Special Leave: Leave to another institution, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval of the NIH funding component is required. To obtain prior approval, the award recipient must submit a letter to the NIH describing the plan, countersigned by his or her department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NIH funding component and will be granted only in unusual situations. Support

from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

I. Termination or Change of Institution: When a grantee institution plans to terminate an award, the NIH funding component must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the individual is moving to another eligible institution, career award support may be continued provided:

A new career award application is submitted by the new institution;

The period of support requested is no more than the time remaining within the existing award period; and

The new application is submitted far enough in advance of the requested effective date to allow the necessary time for review.

The funding component may require a review by an initial review group and/or the appropriate National Advisory Council or Board. Alternatively, review may be carried out by staff within the NIH funding component, depending upon the circumstances.

The Director of the NIH may discontinue an award upon determination that the purpose or terms of the award are not being fulfilled. In the event an award is terminated, the Director of the NIH shall notify the grantee institution and career award recipient in writing of this determination, the reasons therefor, the effective date, and the right to appeal the decision.

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-

43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

This is a generic program announcement for the MRSDA. Because some of the NIH institutes and centers may not participate in this program or may have different award provisions, it is strongly recommended that prospective applicants contact the staff person in the relevant institute or center listed under INQUIRIES early in the planning phase of application preparation. Such contact will help ensure that applications are responsive to the career development goals and policies of the NIH institute or center.

Applications are to be submitted on form PHS 398 (rev. 9/91) and will be accepted on or before the receipt deadlines indicated in the application kit (February 1, June 1 and October 1). Forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, NIH, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/435-0714.

The application must address the following issues:

Candidate

- o Establish the candidate's commitment to a career in biomedical or behavioral research
- o Establish the candidate's potential to develop into a successful independent investigator.

- o Summarize the candidate's immediate and long-term career objectives, explaining how the award will contribute to their attainment.
- o Letters of recommendation. Three sealed letters of recommendation addressing the candidate's potential for a research career must be included as part of the application

Career Development Plan

- o Describe the career development plan, incorporating consideration of the candidate's goals and prior experience. It should describe a systematic plan to obtain the necessary basic biomedical or behavioral science background and research experience to launch or reinitiate an independent research career.
- o Candidates must describe plans to receive instruction in the responsible conduct of research. These plans must detail the proposed subject matter, format, frequency, and duration of instruction as well as the amount and nature of faculty participation. No award will be made if an application lacks this component.

Research Plan

o Describe the research plan and the use of a basic or clinical approach to a biomedical or behavioral problem. The candidate and mentor together must describe the research plan as outlined in form PHS 398 including sections on the Specific Aims, Background and Significance, Progress Report/Preliminary Studies, Research Design and Methods.

Mentor's Statement

o The application must include information on the mentor(s) including information on research qualifications and previous experience as a research supervisor. The application must also include information that describes the nature and extent of supervision that will occur during the proposed award period.

Environment and Institutional Commitment

o The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest including a high-quality research environment with staff capable of productive collaboration with the candidate. The sponsoring institution also must provide a

statement of commitment to the candidate's development into a productive, independent investigator.

Budget

o Budget requests must be provided according to the instructions in form PHS 398. The request for tuition and fees, books, travel, etc., must be justified and specified by category.

To identify the application as a response to this PA, check "YES" on item 2a of page 1 of the application and enter "PA-95-049, Mentored Research Scientist Development Award" and the name of the NIH institute or center that you would like the application to be assigned for funding.

Submit a signed, typewritten original of the application with Checklist, and five signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health
6701 Rockledge Drive, Room 1040 MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness by the Division of Research Grants and responsiveness to the PA by the appropriate institute or center staff. Applications that are complete and responsive to the program announcement will be evaluated for scientific and technical merit by an appropriate peer review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by he appropriate national advisory council or board.

The following review criteria will be applied:

Candidate

- o Commitment to an independent research career;
- o Potential to develop (or evidence of the capacity to develop) as an independent investigator;
- o Quality and breadth of prior scientific training and experience, including, where appropriate, the record of previous research support and publications.

Career Development Plan

- o Likelihood that the plan will contribute substantially to the scientific development of the candidate and the achievement of scientific independence;
- o Appropriateness of the research plan to the career goals of the candidate;
- o Appropriateness of the plan to update conceptual and theoretical knowledge, and the proposed award duration;
- o Consistency of the career development plan with the candidate's prior research and academic experience and the stated career goals;
- o Clarity of the goals and scope of the plan and the need for the proposed research experience; and
- o Quality of the proposed training in the responsible conduct of research.

Research Plan

All candidates for this award will have had previous research experience and in some cases will have been Principal Investigators in other scientific fields. A sound research plan that is consistent with the career development plan and the candidate's level of research development must be provided.

- o Usefulness of the research plan as a vehicle for enhancing existing research skills as described in the career development plan;
- o Scientific and technical merit of the research question, design and methodology, judged in the context of the candidate's previous training and experience;

o Relevance of the proposed research to the candidate's career objectives; and

o adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

Mentor

o Appropriateness of mentor's research qualifications in the area of this application;

o Quality and commitment of the mentor to supervising and guiding the candidate throughout the award period;

o Previous experience in fostering the development of researchers; and

o History of research productivity and support.

Institutional Environment and Commitment

o Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program;

o Adequacy of research facilities and training opportunities;

o Quality of environment for scientific and professional development; and

o Applicant institution's willingness to develop an appropriate mix of research, teaching and administrative responsibilities for the candidate.

Budget

 Justification of budget requests in relation to career development goals and research aims and plans.

AWARD CRITERIA

The NIH institute or center will notify the applicant of the national advisory board or council's action shortly after its meeting. Funding decisions will be made based on the recommendations of the initial review group and council/board, the need for research personnel in specific program areas, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged, especially during the planning phase of the application. Below is a listing of each institute's or center's program or grants management contacts.

Dr. Robin A. Barr
Office of Extramural Affairs
National Institute on Aging
Gateway Building, Room 2C218, MSC 9205
7201 Wisconsin Avenue
Bethesda, MD 20892-9205

Telephone: (301) 496-9322

FAX: (301) 402-9245

Email: Barr@nihniagw.bitnet

Dr. Ernestine D. Vanderveen, Ph.D.

Division of Basic Research

National Institute on Alcohol Abuse and Alcoholism

6000 Executive Boulevard, Suite 402 MSC 7003

Bethesda, MD 20892-7003 Telephone: (301) 443-1273

FAX: (301) 594-0673

Email: tvanderv@willco.niaaa.nih.gov

Ms. Frances Cotter

Division of Clinical and Prevention Research National Institute on Alcohol Abuse and Alcoholism 6000 Executive Boulevard, Suite 505 MSC 7003

Bethesda, MD 20892-7003 Telephone: (301) 443-1207 FAX: (301) 443-8744

Email: fcotter@willco.niaaa.nih.gov

Dr. Mary C. Dufour

Division of Biometry and Epidemiology

National Institute on Alcohol Abuse and Alcoholism

6000 Executive Boulevard, Suite 514 MSC 7003

Bethesda, MD 20892-7003

Telephone: (301) 443-4897

FAX: (301) 443-8614

Email: m.dufour@willco.niaaa.nih.gov

Richard Lymn, Ph.D.

Extramural Programs

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building, Room 5AS-49E

45 Center Drive, MSC 6500

Bethesda, MD 20892-6500

Telephone: (301) 594-5128

FAX: (301) 480-4543 Email: rl28b@nih.gov

The NICHD will accept applications for the K01 under Clinical Rehabilitation Investigator Development Award (CRIDA), but will limit eligibility to candidates who have both clinical training in the rehabilitation related professions (e.g., P.T., O.T., R.N.) and possess doctoral level degrees (e.g., Ph.D., D.Eng., D.Ed.). Individuals supported under CRIDA must be committed to developing careers as independent investigators in medical rehabilitation.

Danuta Krotoski, Ph.D.

National Center for Medical Rehabilitation Research

National Institute of Child Health and Human Development Building

61E, Room 2A03

Bethesda, MD 20892-7510

Telephone: (301) 402-2242

FAX: (301) 402-0832

Email: krotoskd@hd01.nichd.nih.gov

Dr. Lester Gorelic

Division of Extramural Activities

National Cancer Institute

Executive Plaza North, Room 643

Bethesda, MD 20892

Telephone: (301) 496-7344

FAX: (301) 402-4551

Email: gorelicl@dea.nci.nih.gov

(This award is reserved exclusively for minority faculty development)

Dr. Michael Galvin

Division of Extramural Research and Training

National Institute of Environmental Health Sciences

P.O. Box 12233, MD 3-02

Research Triangle Park, NC 27709

Telephone: (919) 541-7825

FAX: (919) 541-2843

Email: galvin@niehs.nih.gov

National Heart, Lung, and Blood Institute

(The NHLBI does not accept applications for the Mentored Research Scientist Award (K01). It does, however, periodically issue Request for Applications (RFA) for the Minority School Faculty Development Award (K01) and the Research Development Award for Minority Faculty (K01) in the NIH Guide for Grants and Contracts.)

Dr. Bettie Graham

National Center for Human Genome Research

Building 38A, Room 610

Bethesda, MD 20892

Telephone: (301) 496-7531

FAX: (301) 480-2770 Email: bg30t@nih.gov

George T. Niederehe, Ph.D.

Division of Clinical and Treatment Research

National Institute of Mental Health

5600 Fishers Lane, Room 18-105

Rockville, MD 20857

Telephone: (301) 443-3264

FAX: (301) 594-6784

Email: gniedere@aoamh4.ssw.dhhs.gov

Kenneth G. Lutterman, Ph.D.

Division of Epidemiology and Services Research

National Institute of Mental Health 5600 Fishers Lane, Room 10-95

Rockville, MD 20857

Telephone: (301) 443-3373

FAX: (301) 443-4045 Email: klutterm@nih.gov

Henry Khachaturian, Ph.D.

Division of Neuroscience and Behavioral Science

National Institute of Mental Health 5600 Fishers Lane, Room 11-103

Rockville, MD 20857

Telephone: (301) 443-8033

FAX: (301) 443-1731

Email: hkhach@helix.nih.gov

Leonard Mitnick, Ph.D.

Office of AIDS Programs

National Institute of Mental Health

5600 Fishers Lane, Room 10-75

Rockville, MD 20857

Telephone: (301) 443-9719

FAX: (301) 443-9719

Email: lmitnick@aoamh2.ssw.dhhs.gov

Mr. Edward Donohue

Division of Extramural Activities

National Institute of Neurological Disorders and Stroke Federal

Building, Room 1016A

Bethesda, MD 20892

Telephone: (301) 496-4188

FAX: (301) 402-4370 Email: ed25b@nih.gov

Dr. Mary Lucas Leveck

Acute and Chronic Illness Branch

National Institute of Nursing Research

Building 45, Room 3AN-12

Bethesda, MD 20892-6300

Telephone: (301) 594-5963

FAX: (301) 480-8260

Email: mleveck@ep.ninr.nih.gov

Leo A. Whitehair, D.V.M, Ph.D.

Comparative Medicine Program

National Center for Research Resources

Westwood Building, Room 857

Bethesda, MD 20892

Telephone: (301) 435-0746

FAX: (301) 480-3660

Email: leow@ep.ncrr.nih.gov

AUTHORITY AND REGULATIONS

The Mentored Research Scientist Development Awards are made under the authority of Title III, Section 301 of the Public Health Service (PHS) Act as amended (Public Law 78-410, as amended, 42 USC 241). The Code of Federal Regulations, Title 42 Part 52, and Title 45 part 74, are applicable to this program. This program is described in the Catalog of Federal Domestic Assistance No. 93.121. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routing education, library, day care, health care or early childhood

development services are provided to children. This is consistent with the phs mission to protect and advance the physical and mental health of the American people.

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